

REMARKS

Claims 1 and 3-44 were pending in the present application. Claim 2 was previously cancelled and claims 5-9 and 14-44 were previously withdrawn from consideration as being drawn to a non-elected invention. By virtue of this response, no claims have been cancelled, amended, nor added. Accordingly, claims 1, 3-4, and 10-13 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Rejections Under 35 USC § 103(a)

A. Claims 1,3-4, and 10-13 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over US 5,910,512 to Conant (Conant). Specifically, the Office Action states:

“Conant fails to teach the claimed kit having separate components. However, it would have been obvious for one of ordinary skill in the art at the time of [sic] the instant invention was made to pack capsaicin and the solvent or the carrier for capsaicin separately and mix them before applying to skin because Conant teaches suspending water soluble capsaicin in various hydrophilic bases before applying to the skin for treating pain and therefore a skilled artisan would have expected capsaicin to be soluble in water and is therefore effective in treating pain, before applying.”

Contrary to the Examiner's reasoning, the rejected claims do not recite capsaicin and the solvent or carrier for capsaicin as being mixed together prior to application to the skin. Applicants emphasize that in claims 1, 3-4, and 10-13, the second composition is a *separate* component of the kit *for cleansing* a bodily surface, and urge the Examiner to review at least paragraphs 11, 12, 21, 44, and 51 of the specification for a more detailed description of the claimed kits and second cleansing compositions. Based on the language of the claims, Applicants disagree that a *prima facie* case of obviousness has been established, as further detailed below.

In order to set forth a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings. Second, there must be a reasonable expectation of success. Lastly, the prior art reference (or references when combined) must teach or suggest all claim limitations. *See* MPEP §2143.

Motivation to modify Conant. Applicants assert that no motivation exists in Conant to make a kit, having as *separate* components, a *first composition* having capsaicin or a capsaicin analog for application to a bodily surface, and a *second composition for cleansing* the bodily surface, as required by claims 1, 3-4, and 10-13. Conant attempts to solve the problem of burning or stinging due to incorporation of strong solvents at the site of topical application. Thus, instead of using harsh solvents such as alcohol, chloroform or ether, Conant describes formulations that include various red algae extracts as a base. As outlined in Examples 1-3, capsicum oleoresin, EDTA, magnesium oxide, red algae extract, and water are mixed together to form one composition. There is no mention of a second composition for cleansing the site of application. Moreover, in Example 4, patients only noted that the composition worked quickly and was easy to apply. They did not complain of any burning or stinging after application. Thus, Applicants submit that any motivation or suggestion to modify Conant to include a second cleansing composition does not exist.

Reasonable expectation of success. A reference may be modified to reject claims as being *prima facie* obvious as long as there is a reasonable expectation of success of making the claimed invention. However, the mere fact that references can be combined or modified does not render the modification or resultant combination obvious unless the prior art also suggests the desirability of the modification or combination (*See*, MPEP §2143.01). As discussed above, there is no motivation or suggestion in Conant to include a second cleansing composition.

Teach or suggest all claim limitations. In order to establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by Conant. Again, Conant does not teach or suggest a second cleansing composition. Accordingly, Applicants submit that the kit recited in claims 1, 3-4, and 10-13 is nonobvious.

Given that Conant fails to establish any one of the criteria necessary for setting forth a *prima facie* case of obviousness, withdrawal of the rejection of claims 1, 3-4, and 10-13 under 35 U.S.C. § 103(a) is respectfully requested.

B. Claims 1, 3-4, and 10-13 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Conant in view of US 6,403,589 to Meert et al. (Meert). Specifically, the Office Action states that Meert suggests administering additional analgesics either separately or sequentially or consecutively or concurrently with draflazine [sic] for treating pain and using the preparation as a kit, but does not teach the amount of capsaicin and the solvent for capsaicin as a separate component. However, the Office Action further states that it would have been obvious for one of ordinary skill in the art at the time of the instant invention to prepare a kit comprising two components, i.e., a first component comprising an effective amount of capsaicin (0.1% to 10% suggested by Conant) and a second component comprising draflazine [sic] and the solvents such as water because Meert suggests that applying a combination of analgesics helps in selecting the timing and sequence of administration, and also requires a lower dose when used individually.

Applicants again disagree that based on the language of the claims, a *prima facie* case of obviousness has been established. Applicants submit that Meert only describes combining a ***nucleoside transport inhibitor with an analgesic*** separately, simultaneously, concurrently, or consecutively for the treatment of pain (*See*, column 8, line 48 to column 9, line 4). The advantage of having the analgesics separated is that appropriate amounts of the each component, and the timing and sequence of administration can be better tailored to individual patients (*See*, column 9, lines 8-12). As previously mentioned, there is no motivation in Conant to provide a kit having a separate cleansing composition. However, even if Conant and Meert were combined, a reasonable expectation of success in making the claimed invention does not exist for the combination, nor does the combination teach or suggest all claim limitations because again, Meert does not teach a kit having as a separate component, any composition for cleansing a bodily surface.

Accordingly, a *prima facie* case of obviousness has not been established, and withdrawal of the rejection of claims 1, 3-4, and 10-13 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524522000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 12, 2006

Respectfully submitted,

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